



FEB 4 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Greg Holland  
Consultant to Advanced Spine Fixation Systems, Inc.  
Holland & Associates  
3722 Avenue Sausalito  
Irvine, California 92606

Re: K992012  
Wiltse System  
Regulatory Class: II  
Product Code: KWQ and MNH  
Dated: November 2, 1999  
Received: November 9, 1999

Dear Mr. Holland:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

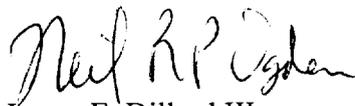
A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

  
James E. Dillard III *for*  
Acting Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K992012

Device Name: Wiltse

**Indications For Use**

The Wiltse System is a pedicle screw system indicated for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The Wiltse System is also intended for anterolateral screw fixation of the noncervical spine. Indications for this system include treatment of cases of spondylolisthesis, fracture, spinal stenosis, deformities (including scoliosis, kyphosis, and lordosis), tumor, pseudoarthrosis, and revision of failed previous fusion surgery. Other indications include degenerative lumbar scoliosis, degenerative spondylolisthesis, and in spinal stenosis, where decompression is required.

The Wiltse System is intended for use by the orthopedic surgeon specializing in spinal surgery. Advanced Spine Fixation Systems Incorporated personnel are available to provide specialized training for surgeons in the use of the device. The attachment points of the sacral screws are intended for the S1 or S2 locations. The sublaminar wire fixation levels range from L1 to L5.

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

NRO for JEP  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K992012

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_  
(Optional Format 1-2-96)